

CLAIMS

1- "Reservoir" microcapsules for the delayed and controlled release of perindopril or a pharmaceutically acceptable salt thereof for oral administration, characterised in that those microcapsules are :

5 ♦ composed of microparticles of perindopril or a pharmaceutically acceptable salt thereof each covered by at least one coating film, that coating film being formed from a composite material comprising :

- at least one hydrophilic polymer A carrying groups ionised at neutral pH,
- at least one hydrophobic compound B, and representing a mass fraction (% by weight in relation to the total mass of the microcapsules) less than or equal to 40,

10 ♦ and have a diameter of less than 1200 microns.

15 2- Microcapsules of perindopril or a pharmaceutically acceptable salt thereof according to claim 1, characterised in that the hydrophilic polymer A is selected from cellulose compounds, copolymers of methacrylic acid and a methacrylic acid ester, copolymers of methacrylic acid and an acrylic acid ester and mixtures thereof.

3- Microcapsules according to claim 2, characterised in that the hydrophilic polymer A is a copolymer of methacrylic acid and methyl methacrylate or a copolymer of methacrylic acid and ethyl acrylate.

20 4- Microcapsules according to any one of claims 1, 2 and 3, characterised in that the hydrophobic compound B is selected from vegetable waxes, hydrogenated vegetable oils, hydrogenated triglycerides and mixtures thereof.

5- Microcapsules according to any one of claims 1 to 4, characterised in that the hydrophobic compound B is a hydrogenated vegetable oil.

6- Microcapsules according to any one of claims 1 to 5, characterised in that the coating film is composed of a mixture of hydrophilic polymer A and hydrophobic compound B in which the weight ratio B/A is between 0.2 and 4.

7- Microcapsules according to any one of claims 1 to 6, wherein the coating film enables :

5 - at a pH of 1.4, a dissolution profile comprising a latent phase of a duration greater than or equal to half an hour - preferably between 1 and 8 hours and more especially from 1 to 5 hours, to be obtained,
- a release phase of perindopril to be obtained at any instant during the latent phase after transition from pH 1.4 to pH 6.8.

10 8- Microcapsules according to any one of claims 1 to 7, characterised in that perindopril is in the form of the tert-butylamine salt.

9- Microcapsules according to any one of claims 1 to 7, characterised in that perindopril is in the form of the arginine salt.

10- Microcapsules according to claim 8 or 9, characterised in that perindopril or a pharmaceutically acceptable salt thereof is deposited onto a neutral core having a diameter of from 50 to 600 microns.

11- Microcapsules according to claim 10, characterised in that the neutral hydrophilic core is made of sucrose, dextrose, lactose or cellulose.

12- Microcapsules according to any one of claims 1 to 11 characterised in that they are combined with indapamide microcapsules.

13- Use of the microcapsules according to any one of claims 1 to 12 for the preparation of pharmaceutical compositions preferably in the form of tablets, powders or gelatin capsules.

14- Pharmaceutical composition characterised in that it comprises microcapsules according to any one of claims 1 to 12.

15- Pharmaceutical composition according to claim 14, characterised in that it is presented in the form of tablets, powders or gelatin capsules, preferably gelatin capsules.

16- Pharmaceutical composition according to claim 14 or 15 for use in the treatment of arterial hypertension and heart failure.